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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,623	08/19/2003	Janos Szamosi	AM100224 P1	4463

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WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,623	SZAMOSI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *15-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to the Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 07/26/07 is acknowledged.

Applicant has overcome the following objection(s) and/or rejection(s) by virtue of the amendment and/or persuasive remarks: (1) The 35 U.S.C. 112, 2nd paragraph rejection of claim 1 has been withdrawn; (2) The 35 U.S.C. §102(b) rejection of claims 1-5, 7-10 and 13 over Wehling *et al.* (US 5,178,878) has been withdrawn; and (3) The 35 U.S.C. §103(a) rejection of claims 1-14 over Korab (US 4,704,269) in view of Mauger (US 5,728,403) has been withdrawn.

Claims 1-31 are pending in this action. Claim 1 has been amended. Claims 15-31 have previously been withdrawn (based on non-elected invention). Claims 1-14 remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended to recite "*a non-effervescent tablet*". This amendment introduces new matter into the claims. The limitation of a "*non-effervescent tablet*" has not been supported by the instant specification. Applicant has referred the Examiner to paragraph 7 of the specification for support for a "non-effervescent" tablet. However, a review of paragraph 7 does not demonstrate that Applicants have support for "non-effervescent" tablet as now claimed. The passage referred to by Applicant merely addresses concerns related to inclusion of effervescent coupled compounds and compares low compression versus high compression tablets. The specification does not specifically disclose or claim "non-effervescent" tablets; thus, the amendment, which introduces a "non-effervescent" tablet into the preamble of claim 1, presents new matter into the claims.

* * * * *

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 5, 7-9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto *et al.* (U.S. Patent No. 5,576,014).

The instant invention is drawn to a non-effervescent tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 kP or lower, and wherein the water soluble excipient and low melting point compound are a fast dissolving granulation.

Mizumoto *et al.* ('014) disclose intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

The claims are anticipated by Mizumoto *et al.*

* * * * *

Claims 1, 4, 5, 7-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu *et al.* (U.S. Patent No. 6,299,904 B1).

The instant invention is drawn to a non-effervescent tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 kP or lower, and wherein the water soluble excipient and low melting point compound are a fast dissolving granulation.

Shimizu *et al.* ('904) disclose a solid preparation, which is a tablet, having fast disintegration that comprises (i) a pharmaceutically active ingredient; (ii) one or more water-soluble sugar alcohols selected from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol and (iii) low-substituted hydroxypropycellulose (see Abstract); (col. 1, lines 8-57); (Claims 1 & 6). Two or more water-soluble sugar alcohols can be used as a mixture in a given ratio (col. 4, line 66 – col. 5, line 2).

Lubricants are disclosed in the composition and include: sucrose fatty acid ester, polyethylene glycol, talc, stearic acid, etc. Polyethylene glycol can be used in an amount of 0.01 to 10 weight parts (col. 6, lines 26-34).

Additives are disclosed in the composition and include: artificial sweeteners such as aspartame, flavorants, lubricants, colorants, stabilizers, disintegrators, etc. (col. 5, line 59 – col. 6, line 25).

The tablets have a hardness of about 2 to about 20 kg (col. 8, lines 5-8).

The claims are anticipated by Shimizu *et al.*

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wehling *et al.* (U.S. Pat. No. 5,178,878) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

The instant invention is drawn to a non-effervescent tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 kPor lower, and wherein the water soluble excipient and low melting point compound are a fast dissolving granulation.

Wehling *et al.* ('878), as discussed above, teach an effervescent dosage form in the form of a rapidly disintegrating tablet, whereby the tablet comprises a pharmaceutical active ingredient (col. 3, lines 45-58); (col. 4, lines 56-62); lubricants such as polyethylene glycol, hydrogenated and partially hydrogenated vegetable oils, animal fats, polyoxyethylene monostearate, light mineral oils and the like in amounts of up to 1.5 wt.% (col. 9, lines 8-20); and water soluble excipients such as saccharides, sugars, invert sugars and the like in amounts of up to 60 wt. % (col. 7, lines 35-51 and Example I). Sweeteners can be added in amounts of up to about 20 wt. %. Suitable sweeteners include aspartame (Table II – col. 13). Suitable excipients

disclosed include mannitol (Tables I & II). Additional polymers include waxes (col. 11, line 50). The tablet has a hardness of about 1.5 kilo pounds (col. 10 lines 30-42).

Additional adjuvants disclosed include flavors, diluents, colors, binders, fillers, compaction vehicles and non-effervescent disintegrants (col. 7, lines 29-34).

Wehling *et al.* do not teach a mixture comprising a low melting point monoglyceride, diglyceride and triglyceride and do not teach selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific mono-, di- and triglyceride mixtures as well as the specific vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Wehling *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in

masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an improved, highly effective and palatable tablet for drug delivery.

* * * * *

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (U.S. Pat. No. 5,576,014) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

Mizumoto *et al.* ('014), as discussed above, teach an intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

While Mizumoto *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Mizumoto *et al.* do not teach a mixture comprising a low melting point monoglyceride, diglyceride and triglyceride and do not teach selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific mono-, di- and triglyceride mixtures as well as the specific

vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Mizumoto *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an effective drug delivery tablet.

* * * * *

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino *et al.* (U.S. Pat. No. 5,501,861).

Makino *et al.* ('861) teach a fast dissolving tablet comprising a pharmacologically active ingredient; carbohydrate including starch sugars, sugar alcohols, tetroses and so on, in amounts of 10 to 90% by weight; and lubricants that include sucrose fatty acid esters, polyethylene glycol, talc and stearic acid (see columns 1, lines 9-15); (col. 3, lines 21-24); (col. 6, lines 1-7). The tablets have a hardness of 3 to 20 kg (Claim 1).

Suitable carbohydrates and sugars taught include sucrose, lactose, glucose and maltose. Sugar alcohols disclosed include sorbitol, mannitol, reduced malt syrup (maltitol), reduced starch saccharides, xylitol and the like (col. 5, lines 1-24) and Examples.

Additives taught include disintegrators, binders, acids, foaming agents, artificial sweeteners such as aspartame, flavorants, lubricants, colorants, etc. (col. 5, lines 55-67).

While Makino *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Given the explicit teachings of Makino *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 07/26/07 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §112, 2nd paragraph rejection:**

Applicant argued, "The omission of the unit of measurement in claim 1 was a typographical error. Claim 1 has been amended to add the unit of measure "kP"."

This argument has been considered and was found persuasive. Accordingly, the 35 U.S.C. 112, 2nd paragraph rejection has been withdrawn.

- **35 U.S.C. §102 rejection over Wehling et al. ('878):**

Applicant argued, "Wehling is directed to a pharmaceutical dosage form that comprises microparticles combined in a tablet with an effervescent disintegration agent (see abstract). Applicant's invention neither requires nor describes an effervescent agent."

This argument has been considered and was found persuasive, by virtue of the amendment to the claim reciting "non-effervescent" tablet. Accordingly, the 35 U.S.C. 102(b) rejection over Wehling et al. has been withdrawn.

- **35 U.S.C. §102 rejection over Mizumoto et al. ('014):**

Applicant argued, "In contrast to Applicant's invention, Mizumoto neither teaches that a water soluble excipient is required (Mizumoto requires at least two saccharides with specified moldabilities) or that a water soluble excipient in combination with a low melting point solid forms a fast dissolving granulation."

This argument was not persuasive since the instant "comprising" claim language permits the presence of additional components, asides from those recited, including the use of more than one saccharide disclosed by Mizumoto. Mizumoto also discloses sucrose fatty acid esters, polyethylene glycol, stearic acid and the like, which would read on the low melting point compounds claimed by Applicant.

Applicant argued, "The listing of lubricants cited by the Examiner is a general listing of lubricants. There is no teaching that a lubricant must be used as in col. 13, lines 32-35. Mizumoto states that the invention 'may contain' other additives, which include lubricants. Further, the lubricants listed in Mizumoto, magnesium stearate, talc and stearic acid have melting

points substantially above 37°C. The other two lubricants (sucrose esters and polyethylene glycols) are classes of compounds that have a range of melting points that include members having melting points above 37°C."

These arguments were not persuasive. The argument that "Mizumoto states that the invention 'may contain'" lubricants, and does not require them" was not persuasive since the term 'may contain' is a positive suggestion, which cannot be ignored in the art. The reference recognizes use of the same components (i.e., polyethylene glycol) as that claimed by Applicant, particularly the components of instant claim 9. Moreover, the tablet of Mizumoto is a quick disintegrating and dissolution tablet.

The anticipation rejection over Mizumoto has been maintained.

- **35 U.S.C. §102 rejection over Shimuzu et al. ('904):**

Applicant argued, "Shimizu does not generally disclose saccharides but a very specific list of sugar alcohols from which the saccharide must be selected. Applicants indicate in paragraph 30 that the monosaccharide mannitol is a preferred saccharide. Shimizu does not even list mannitol."

These arguments were not persuasive, since Shimizu discloses that saccharides can be used in their invention and disclose that the one or more water-soluble sugar alcohols can be chosen from among others, sorbitol and xylitol, which are also claimed by Applicant (see instant claim 5). The argument that "...in paragraph 30, mannitol is disclosed as a preferred saccharide" was not persuasive since "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". See *In re Van Geuns*, 988

F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Mannitol is only one of eleven possible options of the Markush grouping of saccharides being claimed by Applicant in claim 5. The claims do not require the saccharide to be mannitol, but merely provide it as one of many possible options. Thus, the argument that "Shimizu does not even list mannitol" was not persuasive, since Shimizu nonetheless teaches other suitable saccharides of which xylitol and sorbitol are also included and Applicants themselves recite xylitol and sorbitol as one of the suitable saccharides, as shown in instant claim 5.

Applicant argued, "Shimizu discloses a combination of one or more of a limited number of sugar alcohols with a very hydroscopic material hydroxypropylcellulose. Shimizu does not teach a fast dissolving granulation of a water soluble excipient in combination with a low melting point solid."

This argument was not deemed persuasive. Shimizu teach a water soluble excipient (i.e., saccharide) and also teach a low melting point compound, such as polyethylene glycol. The formulation taught by Shimizu is a fast-disintegrating tablet. It is the position of the Examiner that Applicants have not demonstrated any unexpected or superior results, which accrue from the claim limitation of a 'water soluble excipient and low melting point compound being a fast dissolving granulation'. The prior art clearly discloses a fast-disintegrating tablet comprising the same elements (water soluble excipient/low melting point compound) as that being claimed herein by Applicant. The term 'fast dissolving granulation' does not impart a patentable distinction over the explicit reference teachings, which also discuss fast-disintegrating tablets comprising excipients and low melting compounds.

Applicant argued, "The listing of lubricants cited by the Examiner is a general listing of lubricants. There is no teaching that a lubricant must be used as in col. 5, lines 51-60, Shimizu states that the invention 'may further contain' other additives, which include lubricants. Further, the lubricants listed in Shimizu, magnesium stearate, talc and stearic acid have melting points substantially above 37°C. The other two lubricants (sucrose esters and polyethylene glycols) are classes of compounds that have a range of melting points that include members having melting points above 37°C."

These arguments were not persuasive. The argument that "Shimizu states that the invention 'may contain'" lubricants, and does not require them" was not persuasive since the term 'may contain' is a positive suggestion, which cannot be ignored in the art. The reference recognizes use of the same components (i.e., polyethylene glycol) as that claimed by Applicant. The low melting point compounds (i.e., polyethylene glycol) disclosed by Shimizu is sufficient to meet the selective low melting point compounds of instant claim 9, particularly the polyethylene glycol. Moreover, the tablet of Shimizu is a quick disintegrating tablet.

The anticipation rejection over Shimizu has been maintained.

- **35 U.S.C. §103(a) rejection over Wehling et al. ('878) in view of Mauger et al. ('403):**

Applicant argued, "Wehling is directed to a pharmaceutical dosage form that comprises microparticles combined in a tablet with an effervescent disintegration agent (see abstract). Further, there is no teaching that a lubricant or low melting point compound must be used. Applicant's invention neither requires nor describes an effervescent agent."

Applicant's arguments were not persuasive. It is agreed that Wehling teaches an effervescent disintegration agent. However, Applicant's have not established any patentable distinction, which accrues from a 'non-effervescent' tablet as now claimed. Applicants have not demonstrated that the additional effervescent disintegration of Wehling provides for detrimental or adverse effects to the dosage form. The argument that "Wehling does not teach a low melting point compound was not persuasive since Wehling teaches the inclusion of polyethylene glycol and hydrogenated and partially hydrogenated vegetable oils and fats (col. 9, lines 8-20), which would read on the low melting point compounds of instant claim 9.

Applicant argued, "The deficiencies of Wehling are not cured by Mauger. Mauger is directed to a taste masking coating not to a tablet that dissolves readily. Arguably Mauger does not even teach a fast dissolve coating much less a fast dissolving tablet."

These arguments were not persuasive. It is agreed that Mauger teaches a coating. However, Mauger was relied upon to demonstrate the teaching that it is known to incorporate mixtures of mono-, di- and triglycerides, whereby the glycerides provide for aiding in taste-masking of drugs and enables a composition to melt at body temperature. The secondary reference thus teaches that mixtures of mono-, di- and triglycerides are well known and routinely used in the art. The Mauger reference further teaches the use of the selective hydrogenated oils, such as palm kernel oil and hydrogenated cottonseed oil.

The rejection has been maintained.

- **35 U.S.C. §103(a) rejection over Mizumoto et al. ('014) in view of Mauger et al. ('403):**

Applicant argued, ""In contrast to Applicant's invention, Mizumoto neither teaches that a water soluble excipient is required (Mizumoto requires at least two saccharides with specified moldabilities) or that a water soluble excipient in combination with a low melting point solid forms a fast dissolving granulation."

This argument was not persuasive since the instant "comprising" claim language permits the presence of additional components, asides from those recited, including the use of more than one saccharide disclosed by Mizumoto. Mizumoto also discloses sucrose fatty acid esters, polyethylene glycol, stearic acid and the like, which would read on the low melting point compounds claimed by Applicant.

Applicant argued, "The deficiencies of Mizumoto are not cured by Mauger. Mauger is directed to a taste masking coating not to a tablet that dissolves readily. Arguably Mauger does not even teach a fast dissolve coating much less a fast dissolving tablet."

These arguments were not persuasive. Mauger was relied upon to demonstrate the teaching that it is known to incorporate mixtures of mono-, di- and triglycerides, whereby the glycerides provide for aiding in taste-masking of drugs and enables a composition to melt at body temperature. The secondary reference thus teaches that mixtures of mono-, di- and triglycerides are well known and routinely used in the art. The Mauger reference further teaches the use of the selective hydrogenated oils, such as palm kernel oil and hydrogenated cottonseed oil. Thus, Mauger amply remedies the deficiency of Mizumoto.

- **35 U.S.C. §103(a) rejection over Korab ('269) in view of Mauger et al. ('403):**

Applicant argued, "Korab is directed to an effervescent composition. The composition of Korab is an antacid and analgesic powder that is preferably sucrose and sodium free but which produces visible carbon dioxide effervescence when placed in water."

These arguments were persuasive. Accordingly, the 103(a) rejection over Korab in view of Mauger has been withdrawn.

- **35 U.S.C. §103(a) rejection over Makino ('861):**

Applicant argued, "No where in Makino is there any teaching or suggestion that a water soluble excipient combine with a low melting point compound will form a fast dissolve granulation. The addition of lubricants is optional and includes lubricants having melting points substantially above 37°C, such as talc and magnesium stearate."

This argument was not persuasive. Applicant argues the properties obtained from combining a low melting point compound and a water-soluble excipient, such as fast dissolution properties. This argument was not persuasive since Makino also teaches a fast dissolving tablet. The tablet can include low melting point compounds, such as sucrose fatty acid esters and polyethylene glycol, which would read on the low melting point compounds of instant claim 9. While Makino teaches that the lubricants are 'optional' the term is still suggestive of the inclusion of such lubricants. Applicants have not demonstrated any unexpected results which accrue from the water soluble excipient and low melting point compound to be a fast dissolving granulation. The prior art clearly teaches fast dissolving tablets, that can comprise low melting point compounds (i.e., polyethylene glycol) as well as water-soluble excipients (i.e.,

saccharides). The property argued by Applicant (fast dissolving) is insufficient to establish patentability of the claims as presently recited.

The rejection has been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

--No claims are allowed at this time.

This application contains claims 15-31 drawn to an invention nonelected with traverse in the reply filed on 11/09/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

October 08, 2007

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